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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,625

12/15/2003

Geoffrey Allan

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2541

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7590

06/04/2009

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,625	Applicant(s) ALLAN ET AL.	
	Examiner ZOHREH A. FAY	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,6, 7-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8,9 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-17 are presented for examination.

The final rejection of July 10, 2008 is hereby withdrawn and replaced with the instant rejection.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 8, 9, 14, 15, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of one phenyl pyrazoline derivative for lowering serum triglyceride, does not reasonably provide enablement for the use of all 5-lipoxygenase inhibitors for lowering serum triglyceride. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method for treating elevated serum triglycerides using a 5-lipoxygenase inhibitor.

2) The state of the prior art:

The state of the art does not recognize that the treatment of elevated serum triglyceride is due to lipoxgenase inhibitory activity of a lipoxygense inhibitor. See articles Gwori et al. (AJH 1992) and Gowri et al. (Am J physiol Endocrinol metab, 2000) both submitted by the applicant.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

5) The breath of the claims:

The claims are very broad and encompass the use of any 5-lipoxygenase inhibitor for the treatment of elevated serum triglycerides.

6) The amount of direction or guidance provided:

Applicant's specification provides guidance for and it is only enabled for the treatment of elevated serum triglycerides using one 5-lipoxygenase inhibitor, BW755c. No correlation has been established between the inhibition 5-lipoxygenase pathway and treating elevated serum triglycerides. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in applicant's specification either by the enumeration of a sufficient number of the members of the group or by other appropriate language, that the chemicals and chemical combinations included in the claims are capable of accomplishing the desired

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results.” Applicant’s specification does not provide guidance to enable one of ordinary skilled in the art to treat elevated serum triglycerides using any 5-lipoxygenase inhibitor.

7) The presence or absence of working examples;

The examples in applicant’s specification are drawn to the use of one 5-lipoxygenase inhibitor, BW 755c for lowering elevated serum triglycerides.

8) The quantity of experimentation necessary;

Since examples in the specification are drawn to the use of only one 5-lipoxygenase inhibitor for lowering serum triglycerides, and since compound structure and activity for such pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all 5-lipoxygenase inhibitors being capable of lowering elevated serum triglycerides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 161